Venable, Bristow

From: Carchman, Loreen
Sent: Wednesday, August 01, 2001 8:49 AM
To: Osborne, Kevin (PMMC Legal); Venable, Bristow
Cc: Oey, Jan
Subject: FW: Contract Language for Main TES

Kevin,

Here is the proposed timeline for the TES study.

-L

-----Original Message-----
From: Jill Schultz [SMTP:jill.schultz@Covance.Com]
Sent: Sunday, July 08, 2001 9:45 PM
To: Loreen.L.Carchman@pmusa.com
Cc: Jan.Oey@pmusa.com; Roger.A.Walk@pmusa.com
Subject: Contract Language for Main TES

Dear Loreen,

Attached is an example of a Phase II-III contract and an Investigator Agreement for reference in preparing the draft contract for the main TES. We would suggest that two contracts be prepared, one for study design/feasibility and one for the actual study. The first contract could be prepared and signed rather quickly I would think.

The following draft timeline was provided in my minutes of Jan's visit to Covance on 05/10/01:

End of 11/01 Power analysis completed to determine no. of subjects, visits, biomarkers, etc.
End of 11/01 Begin site selection
03/01/02 Protocol milestones finalized
04/15/02 Draft protocol to PM for review (2-week turn around on review)
05/15/02 Final protocol
06/16/02 Contract signed (PM and subcontract with individual sites)
06/15/02 Investigator Meeting
07/15/02 Lead site to start enrollment
09/15/02 Remaining sites to complete start of enrollment

Please let me know if you would like me to set up a conference call to discuss further.

Best regards,

Jill

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